

WHAT IS CLAIMED IS:

1. A method for preparing a pharmaceutical composition comprising:
taking polyoxyethylated castor oil which if diluted 1:10 in water has a pH greater than 6 and aging the polyoxyethylated castor oil by exposing the polyoxyethylated castor oil to a gas comprising oxygen for a period of time, the exposure to the gas over the period of time causing an acidity of the polyoxyethylated castor oil to increase; and
forming a pharmaceutical composition comprising the aged polyoxyethylated castor oil and paclitaxel;
wherein at least 80% of the paclitaxel potency is retained by the pharmaceutical composition after the pharmaceutical composition is stored for at least 7 days at 40°C.
2. The method according to claim 1, further comprising adding an antioxidant to the aged polyoxyethylated castor oil.
3. The method according to claim 1, further comprising adding a pharmaceutically acceptable alcohol to the aged polyoxyethylated castor oil.
4. The method according to claim 3, wherein the pharmaceutically acceptable alcohol is ethanol.
5. The method according to claim 1, further comprising adding a pharmaceutically acceptable glycol to the aged polyoxyethylated castor oil.
6. The method according to claim 5, wherein the pharmaceutically acceptable glycol is propylene glycol or polyethylene glycol.
7. The method according to claim 1, further comprising adding an antioxidant to the pharmaceutical composition.
8. The method according to claim 7, wherein the antioxidant is vitamin E, vitamin C or their derivatives.
9. The method according to claim 7, further comprising adding a pharmaceutically acceptable alcohol to the aged polyoxyethylated castor oil.
10. The method according to claim 1, wherein aging the polyoxyethylated castor oil is performed for at least 30 minutes at a temperature range between 0°C and 70°C.
11. The method according to claim 1, wherein aging the polyoxyethylated castor oil is performed for at least 30 minutes at a temperature range between 30°C and 70°C.

12. The method according to claim 1, wherein aging the polyoxyethylated castor oil is performed for at least 30 minutes at a temperature range between 40°C and 60°C.

13. The method according to claim 1, wherein aging the polyoxyethylated castor oil is performed for at least 7 days at a temperature range between 40°C and 60°C.

14. The method according to claim 1, wherein aging the polyoxyethylated castor oil is performed for at least 30 minutes at a temperature range between 0°C and 70°C by sparging the polyoxyethylated castor oil with air.

15. The method according to claim 1, wherein aging the polyoxyethylated castor oil is performed for at least 30 minutes at a temperature range between 40°C and 60°C by sparging the polyoxyethylated castor oil with air.

16. The method according to claim 1, wherein aging the polyoxyethylated castor oil is performed for at least 30 minutes at a temperature range between 0°C and 70°C by pressurizing the polyoxyethylated castor oil to be at least 1.5 atmospheric pressure.

17. The method according to claim 1, wherein aging the polyoxyethylated castor oil is performed for at least 30 minutes at a temperature range between 0°C and 70°C by pressurizing the polyoxyethylated castor oil to be at least 1.5 atmospheric pressure.

18. The method according to claim 1, wherein at least 90% of the paclitaxel potency is retained by the pharmaceutical composition after the pharmaceutical composition is stored for at least 7 days at 40°C.

19. The method according to claim 1, wherein at least 95% of the paclitaxel potency is retained by the pharmaceutical composition after the pharmaceutical composition is stored for at least 7 days at 40°C.

20. The method according to claim 1, wherein the polyoxyethylated castor oil is selected from the group consisting of: Cremophor® EL and Cremophor® ELP.

21. A method for preparing a pharmaceutical composition of paclitaxel comprising:
taking polyoxyethylated castor oil which if diluted 1:10 in water has a pH greater than 6 and aging the polyoxyethylated castor oil by exposing the polyoxyethylated castor oil to a gas comprising oxygen until the aged polyoxyethylated castor oil, if diluted 1:10 in water, has a pH equal to or less than 5.9; and
forming a pharmaceutical composition comprising the aged polyoxyethylated castor oil and paclitaxel.

22. The method according to claim 21, wherein aging the polyoxyethylated castor oil is performed until the aged polyoxyethylated castor oil, if diluted 1:10 in water, has a pH less than or equal to 5.5.

23. The method according to claim 21, wherein aging the polyoxyethylated castor oil is performed until the aged polyoxyethylated castor oil, if diluted 1:10 in water, has a pH less than or equal to 5.

24. The method according to claim 21, wherein aging the polyoxyethylated castor oil is performed until the aged polyoxyethylated castor oil, if diluted 1:10 in water, has a pH equal to or less than 4.8.

25. The method according to claim 21, wherein aging the polyoxyethylated castor oil is performed until the aged polyoxyethylated castor oil, if diluted 1:10 in water, has a pH between 3.7 and 5.9.

26. The method according to claim 21, wherein aging the polyoxyethylated castor oil is performed until the aged polyoxyethylated castor oil, if diluted 1:10 in water, has a pH between 3.8 and 5.5.

27. The method according to claim 21, wherein aging the polyoxyethylated castor oil is performed until the aged polyoxyethylated castor oil, if diluted 1:10 in water, has a pH between 3.9 and 5.

28. The method according to claim 21, wherein aging the polyoxyethylated castor oil is performed until the aged polyoxyethylated castor oil, if diluted 1:10 in water, has a pH between 4 and 4.8.

29. The method according to claim 21, further comprising adding an antioxidant to the aged polyoxyethylated castor oil.

30. The method according to claim 21, further comprising adding a pharmaceutically acceptable alcohol to the aged polyoxyethylated castor oil.

31. The method according to claim 21, wherein aging the polyoxyethylated castor oil is performed for at least 30 minutes at a temperature range between 0 and 70°C.

32. The method according to claim 21, wherein at least 80% of the paclitaxel potency is retained by the pharmaceutical composition after the pharmaceutical composition is stored for at least 7 days at 40°C.

33. The method according to claim 21, wherein at least 90% of the paclitaxel potency is retained by the pharmaceutical composition after the pharmaceutical composition is stored for at least 7 days at 40°C.

34. The method according to claim 21, wherein at least 95% of the paclitaxel potency is retained by the pharmaceutical composition after the pharmaceutical composition is stored for at least 7 days at 40°C.

35. The method according to claim 21, wherein aging causes the pH of the polyoxyethylated castor oil, if diluted 1:10 in water, to decrease without requiring an agent to be added that functions to increase the acidity of the polyoxyethylated castor oil.

36. The method according to claim 21, wherein the polyoxyethylated castor oil is selected from the group consisting of: Cremophor® EL and Cremophor® ELP.

37. A method for preparing a pharmaceutical composition comprising:

taking polyoxyethylated castor oil which if diluted 1:10 in water has a pH greater than 6 and aging the polyoxyethylated castor oil by exposing the polyoxyethylated castor oil to a gas comprising oxygen for a period of time, the exposure to the gas over the period of time causing an acidity of the polyoxyethylated castor oil to increase; and

forming a pharmaceutical composition comprising the aged polyoxyethylated castor oil, ethanol and paclitaxel;
wherein at least 80% of the paclitaxel potency is retained by the pharmaceutical composition after the pharmaceutical composition is stored for at least 7 days at 40°C.

38. The method according to claim 37, wherein at least 80% of the paclitaxel potency is retained by the pharmaceutical composition after the pharmaceutical composition is stored for at least 7 days at 40°C.

39. The method according to claim 37, wherein at least 90% of the paclitaxel potency is retained by the pharmaceutical composition after the pharmaceutical composition is stored for at least 7 days at 40°C.

40. The method according to claim 37, wherein at least 95% of the paclitaxel potency is retained by the pharmaceutical composition after the pharmaceutical composition is stored for at least 7 days at 40°C.

41. The method according to claim 37, wherein the pharmaceutical composition comprises 500-550 mg/mL of polyoxyethylated castor oil, and 40-60% of ethanol vol/vol.

42. The method according to claim 37, wherein the pharmaceutical composition comprises 527 mg/mL of polyoxyethylated castor oil, and 49.7% of ethanol vol/vol.

43. A method for preparing a pharmaceutical composition of paclitaxel comprising:
taking polyoxyethylated castor oil which if diluted 1:10 in water has a pH greater than 5 and aging the polyoxyethylated castor oil by exposing the polyoxyethylated castor oil to a gas comprising oxygen until the aged polyoxyethylated castor oil, if diluted 1:10 in water, has a pH equal to or less than 4.9; and
forming a pharmaceutical composition comprising the aged polyoxyethylated castor oil, ethanol and paclitaxel;
wherein at least 80% of the paclitaxel potency is retained by the pharmaceutical composition after the pharmaceutical composition is stored for at least 7 days at 40°C.

44. The method according to claim 43, wherein aging the polyoxyethylated castor oil is performed until the aged polyoxyethylated castor oil, if diluted 1:10 in water, has a pH equal to or less than 4.7.

45. The method according to claim 43, wherein aging the polyoxyethylated castor oil is performed until the aged polyoxyethylated castor oil, if diluted 1:10 in water, has a pH between 3.7 and 4.9.

46. The method according to claim 43, wherein aging the polyoxyethylated castor oil is performed until the aged polyoxyethylated castor oil, if diluted 1:10 in water, has a pH between 3.9 and 4.3.

47. The method according to claim 43, wherein at least 90% of the paclitaxel potency is retained by the pharmaceutical composition after the pharmaceutical composition is stored for at least 7 days at 40°C.

48. The method according to claim 43, wherein at least 95% of the paclitaxel potency is retained by the pharmaceutical composition after the pharmaceutical composition is stored for at least 7 days at 40°C.

49. The method according to claim 43, wherein the pharmaceutical composition comprises 500-550 mg/mL of polyoxyethylated castor oil, and 40-60% of ethanol vol/vol.

50. The method according to claim 43, wherein the pharmaceutical composition comprises 527 mg/mL of polyoxyethylated castor oil, and 49.7% of ethanol vol/vol.

51. A pharmaceutical composition comprising:

polyoxyethylated castor oil that has been modified by taking polyoxyethylated castor oil which if diluted 1:10 in water has a pH greater than 6 and aging the polyoxyethylated castor oil by exposing the polyoxyethylated castor oil to a gas comprising oxygen until the aged polyoxyethylated castor oil, if diluted 1:10 in water, has a pH equal to or less than 5.9; and

paclitaxel;

wherein the pharmaceutical composition does not comprise an agent added to the polyoxyethylated castor oil that functions to increase the acidity of the polyoxyethylated castor oil.

52. The pharmaceutical composition according to claim 51, wherein at least 80% of the paclitaxel potency is retained by the pharmaceutical composition after the pharmaceutical composition is stored for at least 7 days at 40°C.

53. The pharmaceutical composition according to claim 51, wherein at least 90% of the paclitaxel potency is retained by the pharmaceutical composition after the pharmaceutical composition is stored for at least 7 days at 40°C.

54. The pharmaceutical composition according to claim 51, wherein at least 95% of the paclitaxel potency is retained by the pharmaceutical composition after the pharmaceutical composition is stored for at least 7 days at 40°C.

55. The pharmaceutical composition according to claim 51, wherein the pharmaceutical composition further comprises ethanol.

56. The pharmaceutical composition according to claim 55, wherein the pharmaceutical composition comprises 500-550 mg/mL of polyoxyethylated castor oil, and 40-60% of ethanol vol/vol.

57. The pharmaceutical composition according to claim 55, wherein the pharmaceutical composition comprises 527 mg/mL of polyoxyethylated castor oil, and 49.7% of ethanol vol/vol.

58. A pharmaceutical composition comprising:

polyoxyethylated castor oil that has been modified by taking
polyoxyethylated castor oil which if diluted 1:10 in water has a pH greater than 5 and
aging the polyoxyethylated castor oil by exposing the polyoxyethylated castor oil to a gas
comprising oxygen until the aged polyoxyethylated castor oil, if diluted 1:10 in water,
has a pH equal to or less than 4.9; and

paclitaxel;

wherein at least 80% of the paclitaxel potency is retained by the pharmaceutical
composition after the pharmaceutical composition is stored for at least 7 days at 40°C.

59. The pharmaceutical composition according to claim 58, wherein at least 90% of
the paclitaxel potency is retained by the pharmaceutical composition after the pharmaceutical
composition is stored for at least 7 days at 40°C.

60. The pharmaceutical composition according to claim 58, wherein at least 95% of
the paclitaxel potency is retained by the pharmaceutical composition after the pharmaceutical
composition is stored for at least 7 days at 40°C.

61. The pharmaceutical composition according to claim 58, wherein the
pharmaceutical composition further comprises ethanol.

62. The pharmaceutical composition according to claim 61, wherein the
pharmaceutical composition comprises 500-550 mg/mL of polyoxyethylated castor oil, and 40-
60% of ethanol vol/vol.

63. The pharmaceutical composition according to claim 61, wherein the
pharmaceutical composition comprises 527 mg/mL of polyoxyethylated castor oil, and 49.7% of
ethanol vol/vol.

64. The pharmaceutical according to claim 61, wherein the concentration of paclitaxel
in the pharmaceutical composition is about 1-20 mg/g.

65. A pharmaceutical comprising:

a sealed vial comprising:

polyoxyethylated castor oil that has been modified by taking
polyoxyethylated castor oil which if diluted 1:10 in water has a pH greater than 6 and
aging the polyoxyethylated castor oil by exposing the polyoxyethylated castor oil to a gas

comprising oxygen until the aged polyoxyethylated castor oil, if diluted 1:10 in water, has a pH equal to or less than 5.9; and

paclitaxel;

wherein the pharmaceutical does not comprise an agent added to the polyoxyethylated castor oil that functions to increase the acidity of the polyoxyethylated castor oil.

66. The pharmaceutical according to claim 65, wherein the vial further comprises ethanol.

67. A pharmaceutical comprising:

a sealed vial comprising

polyoxyethylated castor oil that has been modified by taking polyoxyethylated castor oil which if diluted 1:10 in water has a pH greater than 6 and aging the polyoxyethylated castor oil by exposing the polyoxyethylated castor oil to a gas comprising oxygen until the aged polyoxyethylated castor oil, if diluted 1:10 in water, has a pH equal to or less than 5.9; and

paclitaxel;

wherein at least 80% of the paclitaxel potency is retained by the pharmaceutical after the pharmaceutical is stored for at least 7 days at 40°C.

68. The pharmaceutical according to claim 67, wherein the vial further comprises ethanol.

69. A pharmaceutical comprising:

a sealed vial comprising

polyoxyethylated castor oil that has been modified by taking polyoxyethylated castor oil which if diluted 1:10 in water has a pH greater than 5 and aging the polyoxyethylated castor oil by exposing the polyoxyethylated castor oil to a gas comprising oxygen until the aged polyoxyethylated castor oil, if diluted 1:10 in water, has a pH equal to or less than 4.9; and

paclitaxel;

wherein at least 80% of the paclitaxel potency is retained by the pharmaceutical after the pharmaceutical is stored for at least 7 days at 40°C.

70. The pharmaceutical according to claim 69, wherein the vial further comprises ethanol.